SEXUALLY TRANSMITTED DISEASES (STDs)
Qualitative determination

For in vitro diagnostic use

CE IVD

ORDERING INFORMATIONS

REF: INFET-006-25
RDM Code: 2256478/R
Tests: 25 Reactions: 31 X 2
CND Code: W0105040599
Produttore: BioMol Laboratories s.r.l.

CONTENTS OF THE KIT

The kit consists of reagents for Real-Time PCR amplification
**reagents for the extraction of microbial DNA are not supplied in the kit*

PRODUCT CHARACTERISTICS

Molecular method "NAT" (Nucleic Acid Testing): Qualitative determination of the genome of sexually transmitted microbiological species *Mycoplasma hominis*, *Ureaplasma parvum* and *urealyticum*, *Gardnerella vaginalis*, *Neisseria gonorrhoea*, *Trichomonas vaginalis* and *Mycoplasma genitalium* by PCR (polymerase chain reaction) technique and subsequent detection in PCR-Real-time. Kit optimized for Real-Time PCR instrumentation Biorad CFX96 Dx, Biorad Opus Dx and Agilent AriaDx.

SCIENTIFIC BACKGROUND

Sexually transmitted diseases (STDs) are a leading cause of infertility, long-term disability, ectopic pregnancy, and premature birth. They increase the risk of developing genital cancers and represent a serious medical, social and economic problem for thousands of adults and children around the world.

To date, it has been shown that more than 30 pathogens such as bacteria, viruses, and parasites are transmitted via sexual contact. *Gardnerella vaginalis*, *Neisseria gonorrhoeae*, *Mycoplasma genitalium*, *Trichomonas vaginalis*, *Mycoplasma hominis*, *Ureaplasma urealyticum*, *Ureaplasma parvum*, are the main pathogens responsible for sexually transmitted diseases.

§ The diagnostics landscape for sexually transmitted infections ISBN 978-92-4-007712-6 (electronic version); ISBN 978-92-4-007713-3 (print version) World Health Organization 2023
§ PLoS One. 2023 Mar 6;18(3):e0282439. doi: 10.1371/journal.pone.0282439. eCollection 2023. Simultaneous real-time PCR detection of nine prevalent sexually transmitted infections using a predesigned double-quenched TaqMan probe panel
§ Molecular Detection of Sexually Transmitted Infections in Women with and without Human Papillomaviruses Infection Who Referred to Tehran West Hospitals in Iran. Reports of Biochemistry & Molecular Biology Vol.10, No.3, Oct 2021.
§ Design and Evaluation of a Novel Multiplex Real-Time PCR Melting Curve Assay for the Simultaneous Detection of Nine Sexually Transmitted Disease Pathogens in Genitourinary Secretions. Front. Cell. Infect. Microbiol., 12 November 2019 Sec. Clinical Microbiology Volume 9 - 2019
§ Journal of Medical Microbiology (2014), 63, 162–175. Identification, quantification and subtyping ofGardnerella vaginalis in noncultured clinical vaginalsamples by quantitative PCR
§ PCR for Diagnosis of Male Trichomonas vaginalis Infection with Chronic Prostatitis and Urethritis. Korean J Parasitol Vol. 50, No. 2: 157-159, June 2012.
§ A comparative study of three different PCR assays for detection of Mycoplasma genitalium in urogenital specimens from men and women. Journal of Medical Microbiology (2008), 57, 304–309.
§ Specific and Sensitive Detection of Neisseria gonorrhoeae in Clinical Specimens by Real-Time PCR. JOURNAL OF CLINICAL MICROBIOLOGY, Nov. 2005, p. 5653–5659 Vol. 43, No. 11 doi: 10.1128/JCM.43.11.5653–5659.2005.
§ Sequence of cDNA coding for a 65 kDa adhesive protein for the specific detection of Trichomonas vaginalis by PCR. FEMS Microbiology Lcrters 12Y (IYYS) 21-26.
§ Detection of Mycoplasma genitalium by PCR Amplification of the 16S rRNA Gene. JOURNAL OF CLINICAL MICROBIOLOGY, Jan. 2003, p. 261–266. DOI: 10.1128/JCM.41.1.261–266.2003
§ Species Identification and Subtyping of Ureaplasma parvum and Ureaplasma urealyticum Using PCR-Based Assays. JOURNAL OF CLINICAL MICROBIOLOGY, Mar. 2000, p. 1175–1179.

CLINICAL SIGNIFICANCE

Gardnerella vaginalis is a predominant anaerobic bacterium responsible for bacterial vaginosis (BV) in women. Gonorrhea, caused by the bacterium *Neisseria gonorrhoeae*, is the second most common STD after *Chlamydia trachomatis* infection. Infections can lead to long-term consequences, such as pelvic inflammatory disease, chronic pelvic pain, ectopic pregnancy, neonatal conjunctivitis, and infertility. *Neisseria gonorrhoeae* infection has also been reported to increase the risk of human immunodeficiency virus (HIV) infection. *Mycoplasma genitalium* accounts for approximately 15-20% of cases of nongonococcal urethritis and 40% of cases of persistent or recurrent urethritis. Trichomoniasis, an infection caused by the protozoan *Trichomonas vaginalis*, can be associated with urethritis and prostatitis. *Mycoplasma hominis* is commonly implicated in the genesis of bacterial vaginosis and pelvic inflammatory disease. *Ureaplasma* is a bacterium of the mycoplasma family, responsible for the onset of infections especially at the genital level. There are two species of *Ureaplasma*: *urealyticum* and *parvum*.

The product INFET-006 allows the qualitative determination of the genome of sexually transmitted microbiological species *Mycoplasma hominis*, *Ureaplasma parvum* and *urealyticum*, *Gardnerella vaginalis*, *Neisseria gonorrhoea*, *Trichomonas vaginalis* and *Mycoplasma genitalium* by PCR (polymerase chain reaction) technique and subsequent detection in Real-time PCR.

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ISO 9001 :2015
ISO 13485:2021

ED.1 REV.0 of 01/10/2024

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DESCRIPTION	LABEL	VOLUME	STORAGE
		INFET-006-25	
Mix buffer and Taq polymerase enzyme	Mix Real-Time PCR 5X	1 x 310 µl	-20° C
Mix oligonucleotides and probes Mycoplasma hominis, Ureaplasma parvum and urealyticum, Gardnerella vaginalis	Mix MST-1 10 X	1 x 77,5 µl	-20° C
Mix oligonucleotides and probes Neisseria gonorrhoea, Trichomonas vaginalis, Mycoplasma genitalium	Mix MST-2 10X	1 x 77,5 µl	-20° C
Deionized H_20	Deionized H_20	1 x 1 ml	-20° C
Genomic DNA or recombinant DNA	Control +	1 x 40 µl	-20° C
Genomic DNA or recombinant DNA	Control -	1 x 40 µl	-20° C

TECHNICAL CHARACTERISTICS

COD. INFET-006- 25

STABILITY	18 months
REAGENTS STATUS	Ready to use
BIOLOGICAL MATRIX	Microbial DNA in vaginal swab and biological fluids
POSITIVE CONTROLS	Recombinant DNA for at least 3 analytical sessions
VALIDATED INSTRUMENTS	Biorad CFX96 Dx, Biorad Opus Dx and Agilent AriaDx
TECHNOLOGY	Real-time PCR; Oligonucleotides and specific probes
RUNNING TIME	85 min
THERMAL CYCLING PROFILE	1 cycle at 95 °C (10 min); 40 cycles at 95 °C (15 sec) + 57 °C (25 sec) + 72 °C (40 sec)
ANALYTICAL SPECIFICITY	Absence of non-specific pairings of oligonucleotides and probes; absence of cross-reactivity
LIMIT OF DETECTION (LOD)	≥ 0,016 ng of host-cell genomic DNA
LIMIT OF BLANK (LOB)	0% NCN
REPRODUCIBILITY	99,9%
DIAGNOSTIC SPECIFICITY / DIAGNOSTIC SENSITIVITY	100% /98%

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